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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT - 3 1997

Via Federal Express

WARNING LETTER

Leon C. LaHaye, M.D.
LaHaye Center for Advanced Eye Care
201 Rue Iberville, Suite 800
Lafayette, Louisiana 70508

Dear Dr. LaHaye:

You were inspected during the period of August 4-8, 1997, by Mr. Henry E. Sanchez and Mr. Jose R. Hernandez, investigators from the Food and Drug Administration's (FDA) New Orleans District Office. The purpose of the inspection was to determine whether your activities regarding your [redacted] of the [redacted] for [redacted] treatment of [redacted] complied with applicable FDA regulations. Your [redacted] is a device as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Background

On February 19, 1997, FDA received your [redacted] for evaluation of an [redacted] for use in [redacted] treatment of [redacted]. FDA conditionally approved that [redacted] on March 21, 1997, to treat [redacted]. That conditional approval letter identified numerous deficiencies in your [redacted] which were to be corrected within 45 days of March 21, 1997. In a letter dated May 10, 1997, you responded to these deficiencies. By letter, dated June 11, 1997, FDA informed you that your [redacted] remained conditional because you had not adequately addressed deficiencies 2 and 4 cited in the March 21 FDA letter.

On August 1, 1997, FDA sent you a letter, as a follow-up to a phone conversation on July 30, in which you were requested to certify that you would not treat patients beyond the conditions of approval of your [redacted] Your certification was received by the FDA via facsimile on August 4.

You submitted [redacted] to your [redacted] July 25, 1997, responding to the deficiencies listed in the June 11 FDA letter, and [redacted] on July 28, 1997, notifying FDA of [redacted] of your [redacted] and

the [redacted] suggested modifications to you[redacted] document. FDA notified you, in a letter dated August 27, 1997, that your [redacted] remained conditionally approved because you did not adequately address deficiency 1 cited in the June 11 letter. Your response to the August 27 letter was received on September 12, 1997, and is presently under review by the Office of Device Evaluation (ODE). Finally, you met with ODE on September 12 to discuss its remaining concerns with your [redacted]

The Office of Compliance (OC), through its Division of Bioresearch Monitoring (DBM), requested the August inspection of your facility. This inspection was conducted under a program designed to ensure that data and information contained in applications for [redacted], or [redacted] submissions are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of the scientific [redacted].

Inspectional Findings

The inspection revealed serious deviations from Title [redacted] Code of Federal Regulations, ([redacted], [redacted] - [redacted] and Part [redacted] The deficiencies noted during the inspection were listed on form FDA-483, "Inspectional Observations," which was presented to and discussed with you at the conclusion of the inspection. Deviations noted include the following:

- [redacted] was performed on approximately [redacted] subjects between March 21, 1997, when [redacted] received conditional approval, and June 11, 1997, when [redacted] for the [redacted] was granted. The regulations pertaining to [redacted] CFR Part [redacted] require that a [redacted] obtain [redacted] prior to initiating an [redacted] See [redacted].

- You exceeded the [redacted] patient limit of your conditional approval by treating [redacted] subjects between March 21 and the date of the inspection. A [redacted] is responsible for ensuring that an [redacted] is conducted according to conditions of approval imposed by FDA. See [redacted].

- A revised version of the [redacted] was not approved by the [redacted] until early July and not placed into use until the end of July. Moreover, at the time of the inspection, none of the [redacted] treated since conditional approval of the [redacted] had received copies of their [redacted]. It is the responsibility of the [redacted] to ensure that [redacted] is obtained in accordance

with FDA regulations for the [redacted] (see [redacted] and [redacted]) and that a copy of the [redacted] is given to the person [redacted] (see [redacted]).

- Your study does not include signed agreements from [redacted] yet your associates examined subjects pre- and post-surgery and evaluated their condition. These evaluations are part of the [redacted]. All individuals participating in any phase of an [redacted] must sign agreements containing specific elements, as set forth in [redacted].

- There is no evidence that any of your educational and promotional materials have been reviewed and approved by your [redacted]. Patient brochures and similar educational materials describing [redacted] are seen as part of the [redacted] and [redacted] process. They are a form of advertisement for the purpose of [redacted] review of these materials is necessary to ensure that the information provided to [redacted] is not misleading.

- Your folder of information concerning the [redacted] procedure, which serves as your patient brochure, does not comply with regulations for [redacted] concerning [redacted] and other practices, as described in [redacted]. An [redacted] cannot be represented as [redacted] for the purposes for which it is being [redacted]. Such statements as "One of the most advanced [redacted] surgical procedures..," "...allow surgeons to correct a wide range of [redacted] disorders," "...allows more rapid healing and [redacted] recovery," "the [redacted] Advantage," etc., are therefore in violation of the regulations. Also, nowhere in the brochure is it stated that this is an [redacted] limited by Federal (or United States) Law to [redacted] use.

- You solicited fellow ophthalmologists to participate in your [redacted] as co-managers of [redacted], with a "Dear Doctor" mass mailing. FDA considers an undirected mass mailing an inappropriate means of soliciting fellow [redacted]. Such a mailing is considered promotional.

The deviations listed above are not intended to be an all-inclusive list of deficiencies. It is your responsibility as a [redacted] to ensure that your [redacted] is conducted in accordance with the signed agreement, the [redacted], and applicable FDA regulations for protecting the rights, safety, and welfare of [redacted] under your care.

We acknowledge the fact that, since the close of FDA's inspection, you have obtained [redacted] approval and have an [redacted] approved [redacted] available. Moreover, you have certified that you have discontinued use of your [redacted] pending receipt of approval for expansion of your [redacted] and have met with ODE to discuss its concerns with your [redacted] Please advise this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the remaining violations listed above and to prevent recurrence of similar violations in current or future studies. Please send your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch II (HFZ-312), 2098 Gaither Road, Rockville, Maryland 20850, Attention: Jean Toth-Allen, Ph.D.

A copy of this letter has been forwarded to our New Orleans District Office, 4298 Elysian Fields Avenue, New Orleans. Louisiana 70122. We request that a copy of your response be sent to that office.

We want you to be aware that failure to comply with the law may result in further regulatory action against you or the device by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

If you have any questions, you may contact Jean Toth-Allen at (301) 594-4723, ext. 141.

Sincerely yours,

Lillian J. Gill

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health